



DEPARTMENT OF HEALTH & HUMAN SERVICES

August 7, 2000

Food and Drug Administration  
Rockville, MD 20857

Carol Brophy  
One Maritime Plaza  
Sixth Floor  
San Francisco, California 94111

Dear Ms. Brophy,

This letter responds to your telephone inquiry regarding the review status of a petition submitted by Occupational Knowledge International (Docket # 00P-1210) on March 6, 2000. The petitioner requests that the agency initiate a formal review of the safety of coal tar, specifically regarding carcinogenicity. Additionally, the petitioner requests that the agency restrict products containing coal tar to prescription sale and add warnings. Coal tar is currently marketed in OTC drug products.

The agency is currently reviewing and analyzing the data provided in the petition and in an amendment submitted by the petitioner on June 1, 2000. The original petition, the amendment, and any comments are available in the public docket. Once the agency completes its review of all of the data in the petition and in the comments, it will respond to the issues raised by the petitioner. If you have any relevant data that you would like the agency to consider, please submit written comments to Docket # 00P-1210 at the address listed below.

Dockets Management Branch (HFA-305), Room 1-23  
12420 Parklawn Drive  
Rockville, MD 20857

Sincerely yours,

Charles J. Ganley, M.D.  
Director, Division of OTC Drug Products  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research  
Food and Drug Administration

00P-1210

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